UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/495,186	02/01/00	MCMICHAEL J	13024/35946

HM22/0703

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EXAMINER	
WILSON,M	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/495,186	MCMICHAEL ET AL.	
	Examiner	Art Unit	
	Michael Wilson	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Applicant's arguments filed 4-20-01, paper number 10, have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-20 are pending and under consideration in the instant application. The Declaration filed 4-20-01 has been entered and considered.

Specification

1. The disclosure is objected to because of the following informalities: "injected" on page 14, line 15. It is unclear what applicants consider an "injected" tympanic membrane. In addition, the first line of the specification needs updated regarding the patent numbers of the priority documents. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1-7 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating respiratory congestion in an allergy patient comprising: sublingually administering in a manner so as not to effect gene transfer an effective amount of DNA in a pharmaceutically-acceptable vehicle to an allergy patient having respiratory congestion wherein said method results in reduction of respiratory congestion, does not reasonably provide enablement for treating allergy symptoms not associated with respiratory congestion using any route of delivery. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-7 are directed toward a method of treating allergy symptoms using DNA and reducing the allergy symptoms not associated with respiratory congestion. The purpose of administering DNA to allergy patients is to treat allergy symptoms (page 3, line 28). The state of the art at the time of filing was that allergies include immune reactions against bee stings, bug bites, snake bites, pollen, dust, foods, inhalants, chemicals et al. Symptoms of allergies include respiratory congestion, swelling, irritation, difficulty breathing, vasoconstriction and anaphylactic shock. Swelling, irritation, difficulty breathing and anaphylactic shock can be caused by respiratory congestion. The specification and the art do not distinguish which allergy symptoms are "not associated with respiratory congestion" as claimed. Therefore, it is unclear what allergy symptoms are not associated with respiratory congestion as claimed (see 112/2nd rejection).

The specification teaches administering DNA to a patient with broad spectrum allergies to foods and inhalants and obtaining the patients "preexposure state" (page 17, lines 22-29). Example XXXI suggests treating a patient with "sensitivity to grasses and hay leading to congestion, headache, irritated eyes and lethargy" prior to exposure or shortly thereafter results in "complete relief." Examples XXXII and XXXIII are prophetic and do not teach the symptoms prior to DNA administration or the symptoms that are ameliorated after DNA administration. Overall, applicants have not provided a correlation between delivery of DNA to treating symptoms not associated with respiratory congestion.

Claims 1 and 3-6 encompass using any route of DNA delivery and claim 7 recites the limitation of administering the DNA sublingually, subcutaneously, intravenously, intramuscularly or intrathecally. Examples I-X require sublingual administration to relieve congestion. Examples XXX-XXXI require sublingual administration but do not enable treating symptoms of allergies not associated with respiratory congestion for reasons cited above. Examples XXXII and XXXIII do not teach the route of administration and do not enable treating symptoms of allergies not associated with respiratory congestion for reasons cited above. The specification does not correlate the administration of DNA sublingually to administration of DNA subcutaneously, intravenously, intramuscularly, intrathecally or any other route of delivery such that therapeutic results could be obtained. It would require one of skill undue experimentation to determine the parameters required to deliver DNA subcutaneously, intravenously, intramuscularly, intrathecally or using any other route of delivery such that therapeutic results could be obtained. Therefore, the specification only enables treating respiratory congestion in an allergy patient using DNA administered sublingually.

Applicants argue that US patent 5,955,442 is not limited to sublingual administration in the treatment of respiratory congestion. Applicants argument is not persuasive because each application is examined on its own merits. Applicants clarifies that Ex. XXX refers to preexposure to heavy air; however, it cannot be determined what allergens are in "heavy air". Applicants argue that the examples support treatment of symptoms of allergies beyond respiratory congestion. Applicants argument is not persuasive because applicants have not pointed to one

symptom of allergies that is "not associated with respiratory congestion" that is relieved using DNA, because all of the symptoms that are alleviated in the disclosure are associated with respiratory congestion and because the claims require treating allergy symptoms not associated with respiratory congestion. Likewise, the declaration by Dr. McMichael is not persuasive because all of the symptoms that are alleviated in the declaration (airway constriction, dyspnea, cough) are "associated" with respiratory congestion because they related to a congested airway.

3. Claims 8-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating respiratory congestion in a patient with asthma comprising: sublingually administering in a manner so as not to effect gene transfer and expression a therapeutically effective amount of DNA in a pharmaceutically-acceptable vehicle to an asthma patient with respiratory congestion, wherein said method results in a reduction in respiratory congestion, does not reasonably provide enablement for treating a symptom of asthma not associated with respiratory congestion or using any route of delivery. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 8-14 are directed toward a method of treating asthma symptoms and reducing the allergy symptoms not associated with respiratory congestion. The purpose of administering DNA to asthma patients is to treat asthma symptoms (page 4, line 3). The state of the art at the time of filing was that asthma symptoms include an increase in mucous production, plugs of mucous in the airways, wheezing, shortness of breath and constriction of the airways (1988, The Textbook

of Respiratory Medicine, John F. Murray, ed., W.B. Saunders Company, Philadelphia; see page 1038, column 2, line 27-31). The specification and the art do not distinguish which asthma symptoms are "not associated with respiratory congestion" as claimed. Therefore, it is unclear what asthma symptoms are not associated with respiratory congestion as claimed (see 112/2nd rejection).

The specification teaches administering DNA to an asthma patient with restricted physical activity resulted in the patient becoming able to run several miles daily and work without undue fatigue and improved respiratory function (page 19, lines 8-19). Examples I-X teach decreasing respiratory congestion in patients with COPD, rhinitis and sinusitis. Respiratory congestion as disclosed in examples I-X correlate with respiratory congestion in asthma patients such as overproduction of mucous, thick mucous, nasal congestion and sinus congestion. It would require one of skill undue experimentation to determine how to use DNA to treat symptoms that are not associated with respiratory congestion because the invention relates to degrading DNA in sputum to increase the ability of the patient to evacuate sputum from the airways (page 5, line 19). Therefore, the claims should be limited to treating respiratory congestion in asthma patients.

Claims 8 and 10-13 encompass using any route of DNA delivery and claim 14 recites the limitation of administering the DNA sublingually, subcutaneously, intravenously, intramuscularly or intrathecally. Examples I-X require sublingual administration to relieve congestion. Examples XXXIV-XXXV require sublingual administration. The specification does not correlate the administration of DNA sublingually to administration of DNA subcutaneously, intravenously,

intramuscularly, intrathecally such that therapeutic results could be obtained. The specification only enables treating respiratory congestion in an asthma patient using DNA administered sublingually for reasons of record.

Applicants argue that the examples support treatment of asthma symptoms that are "not associated with respiratory congestion." Applicants argument is not persuasive because applicants have not pointed to one symptom of asthma that is "not associated with respiratory congestion" that is relieved using DNA, because all of the symptoms that are alleviated in the disclosure are "associated with respiratory congestion" and because the claims require treating asthma symptoms not associated with respiratory congestion. Likewise, the declaration by Dr. McMichael is not persuasive because all of the symptoms that are alleviated in the declaration (airway constriction, dyspnea, cough) are "associated" with respiratory congestion because they related to a congested airway.

4. Claims 1-15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 are indefinite because "the allergy symptoms not associated with respiratory congestion" lacks antecedent basis in the claim. The metes and bounds of what applicants consider allergy symptoms "not associated with respiratory congestion" because all of the symptoms of allergies relate to respiratory congestion. E.g. swelling, redness and pain are caused

by an inflammatory response and excess mucous. Therefore, the phrase "not associated with respiratory congestion" is indefinite.

Claim 8 are indefinite because the metes and bounds of what applicants consider asthma symptoms "not associated with respiratory congestion" because all of the symptoms of asthma relate to respiratory congestion. E.g. wheezing, difficulty breathing and fatigue are caused by respiratory congestion. Therefore, the phrase "not associated with respiratory congestion" is indefinite.

Claim 20 does not further limit claim 15 because it recites the DNA is in eardrops which is already in claim 15.

Claim Rejections - 35 USC § 102

5. Claims 8-14 remain rejected under 35 U.S.C. 102(e) as being anticipated by McMichael (U.S. Patent 6,100,244, 8-8-00), McMichael (U.S. Patent 5,955,442, 9-21-99), McMichael (U.S. Patent 5,726,160, 3-10-98) and McMichael (US Patent 6,096,721, 8-1-00).

These references teach treating symptoms of asthma by administering liquid drops of 0.0006 mg of DNA sublingually to asthma patients ('244, column 2 lines 1-37; column 6, line 61; '721, column 2, lines 1-37; column 6, line 54; '442, column 4, line 4; '160, column 4, line 3). The symptoms alleviated in '244, '442, '160, '721 are "not associated with respiratory congestion" as claimed because the symptoms treated are the same as those disclosed in the instant application

and because the metes and bound of what asthma symptoms are "not associated with respiratory congestion" is unclear.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing dates of the references, they constitute prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the references was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants argue that the rejection over '244 should be withdrawn because the disclosures of '244 was derived solely from Dr. McMichael and not from co-inventors Dr. McMichael and Dr. Allen, the inventors of the instant invention. If Dr. Allen did not invent the claimed invention, then Dr. Allen should be deleted as an inventor in the instant application. Furthermore, '244 discloses treating asthma (claims 2 and 3). Therefore, the declaration is not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

6. Claims 1-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael (U.S. Patent 6,100,244, 8-8-00), McMichael (U.S. Patent 5,955,442, 9-21-99), McMichael (U.S. Patent 5,726,160, 3-10-98) or McMichael (US Patent 6,096,721, 8-1-00) in view of Kuby (1992, Immunology, Kuby, ed., W.H. Freeman and Company, page 360).

McMichael teaches treating respiratory congestion by administering liquid drops of 0.0006 mg of DNA sublingually to patients with respiratory congestion such that symptoms of respiratory congestion is reduced ('244, column 2 lines 1-37; column 6, line 61; '721, column 2, lines 1-37; column 6, line 54; '442, column 4, line 4; '160, column 4, line 3). McMichael does not teach administering the DNA to a patient with allergy symptoms.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating respiratory congestion as taught by McMichael to treat respiratory congestion in allergy patients to reduce respiratory congestion (Kuby, page 360, column 2, first full paragraph). One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of McMichael in allergy patients to relieve the allergies. The symptoms alleviated in '244, '442, '160, '721 are "not associated with respiratory congestion" as claimed because the symptoms treated are the same as those disclosed in the instant application and because the metes and bound of what allergy symptoms are "not associated with respiratory congestion" is unclear. Therefore, the combined teachings of McMichael and Kuby obviate claims 1-7.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art at the time the invention was made would have been motivated to use the method of McMichael in allergy patients to relieve respiratory congestion in allergy patients.

Double Patenting

7. Claims 1-7 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,955,442 or claims 1-7 of U.S. Patent No. 5,726,160 in view of Kuby (1992, Immunology, Kuby, ed., W.H. Freeman and Company, page 360). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of '442 and '160 encompass treating respiratory congestion in a broad genus of patients. The species of treating allergy patients as in claims 1-7 of the instant application is an obvious variant of the claims in '442 and '160. While '442 and '160 do not disclose treating symptoms not associated with respiratory congestion or treating allergy patients, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating respiratory congestion in '442 or '160 in allergy patients as claimed because allergy patients also have respiratory congestion (Kuby, page 360, column 2, first full paragraph). Claims 1, 3-7 encompass numerous routes of delivery while claim 2 is limited to sublingual delivery; the claims of '442 and '160 are limited to sublingual administration. Therefore,

sublingual administration is an obvious species in the claimed invention as broadly claimed (claims 1 and 3-7).

The symptoms alleviated in '442 and '160 are "not associated with respiratory congestion" as claimed because the symptoms treated are the same as those disclosed in the instant application and because the metes and bound of what allergy symptoms are "not associated with respiratory congestion" is unclear (see 112/2nd above).

8. Claims 8-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,955,442 or claims 1-7 of U.S. Patent No. 5,726,160 in view of Murray (1988, The Textbook of Respiratory Medicine, John F. Murray, ed., W.B. Saunders Company, Philadelphia, page 1038) or over claims 1-7 of U.S. Patent No. 6,100,244. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of '442 and '160 encompass treating respiratory congestion in a broad genus of patients. The species of treating asthma patients as claimed in the instant application is an obvious variant of the claims in '442 or '160. While '442 and '160 do not disclose treating asthma patients, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating respiratory congestion as claimed in '442 or '160 in asthma patients because asthma patients have respiratory congestion (Murray; page 1038, column 2, lines 27-31). Claims 8 and 10-14 encompass numerous routes of delivery while claim 9 is limited to sublingual administration; claims of '442 and '160 are limited to sublingual

administration. Sublingual administration is an obvious species in the claimed invention as broadly claimed (claims 8 and 10-14). In addition, '244 specifically claims delivering liquid drops of 0.0006 mg DNA in water, saline, albumin or dextrose to asthma patients with shortness of breath while the instant claims encompass delivering DNA to any asthma patient. Therefore, the claims of '244 are an obvious species of claims 8-14 in the instant application.

The symptoms alleviated in'442 and '160 are "not associated with respiratory congestion" as claimed because the symptoms treated are the same as those disclosed in the instant application, because '244 treats "shortness of breath" and because the metes and bound of what asthma symptoms are "not associated with respiratory congestion" is unclear (see 112/2nd above).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

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